K000715

MAR 31 2000

Attachment 3

Summary of Safety and Effectiveness

General Provisions	Trade Name: VISTA BRITE TIP and ENVOY Guiding Catheter Common/Classification Name: Percutaneous Catheter
Name of Predicate Devices	• Cordis Corporation VISTA BRITE TIP Guiding Catheter • Cordis Endovascular Systems, Inc. ENVOY Guiding Catheter
Classification	Class II
Performance Standards	The FDA under section 514 of the Food, Drug and Cosmetic Act has not established performance standards.
Intended Use and Device Description	The VISTA BRITE TIP Guiding Catheters are intended for use for intravascular introduction of interventional/diagnostic devices into the coronary or peripheral vascular systems. The ENVOY Guiding Catheters are intended for use in the coronary, peripheral, and neuro vasculature for intravascular introduction of interventional/diagnostic devices. The device description of the VISTA BRITE TIP and ENVOY Guiding Catheters is as follows. • 5 French • Single lumen catheter featuring a nylon body reinforced with a tightly wound stainless steel braid wire • The transition segments are designed with nylons of different durometers (stiffness) to provide a gradual decrease in material stiffness from the catheter body to the tip.
Biocompatibility	All materials used in the VISTA BRITE TIP and ENVOY Guiding Catheters are biocompatible.
Summary of Substantial Equivalence	The VISTA BRITE TIP and ENVOY Guiding Catheters are substantially equivalent to the previously cleared VISTA BRITE TIP and ENVOY Guiding Catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 2000

Mr. Dennis S. Griffin
Manager, Regulatory Affairs
Cordis Corporation
P.O. Box 025700
Miami FL, 33102-5700

Re: K000715
Trade Name: ENVOY and VISTA BRITE TIP Guiding Catheters
Regulatory Class: II (two)
Product Code: DQY
Dated: March 1, 2000
Received: March 2, 2000

Dear Mr. Griffin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number (if known)	K000715
Device Name	VISTA BRITE TIP and ENVOY Guiding Catheters
Indications for Use	The VISTA BRITE TIP Guiding Catheters are intended for use for intravascular introduction of interventional/diagnostic devices into the coronary or peripheral vascular systems. The ENVOY Guiding Catheters are intended for use in the coronary, peripheral, and neuro vasculature for intravascular introduction of interventional/diagnostic devices.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Christopher Hess for Dillard

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K000715

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)